

April 8, 2020

DBHDS recognizes the risks of discontinuing clozapine in a patient receiving this treatment for a mental health condition and is supportive of the guidance issued by the FDA related to its dispensing during this pandemic. (See <https://www.fda.gov/media/136317/download>). While a formal statement is not needed since there is guidance issued by the FDA, this communication offers clarification for the FDA guidance.

Obtaining labs for patients being treated with clozapine needs to be determined on a case-by-case basis in coordination with the prescriber's rationale. Prescribers and pharmacies already have discretion to order and dispense clozapine without the required labs as long as they have a Dispensing Rationale. The key points for dispensing clozapine during this pandemic include:

- Pharmacies can dispense clozapine without getting labs first regardless of monitoring frequency.¹
- A "Dispensing Rationale" still needs to be submitted via the REMS site.² This is usually allowed up to 3 times within a 6-month timeframe.
- Pharmacists must consult with the provider FIRST before dispensing, to verify and document they will dispense without labs.
- In accordance with standard practice, pharmacists should use "professional judgement" when dispensing, *i.e., if client has had a trend towards low ANC's then discussing with the provider and documenting the provider's "Treatment Rationale" is recommended.*³
- If clients are able to still get labs, they should, IF they are able to do so safely (at home self-testing, or if labs are set up to accept clients properly to avoid the spread of COVID-19, etc.)
- The FDA does not intend to take enforcement action against sponsors or others for accommodations made regarding laboratory testing. Regardless, documentation should be maintained for any actions taken.⁴
- If a client drops down automatically to a lower weekly lab draw due to no lab taken or a late draw, the provider should call the REMS and have the client changed to the correct one.

¹ Predispose Authorization (PDA) Fact Sheet for Outpatient

Pharmacies: https://www.clozapinerems.com/CpmgClozapineUI/rems/pdf/resources/Clozapine_REMS_PDA_Fact_Sheet.pdf

² Provides pharmacies with an opportunity to apply clinical judgement and continue to dispense clozapine to enrolled patients [when a patient's prescriber is not registered with the REMS program] https://www.clozapinerems.com/CpmgClozapineUI/rems/videos/outpatientPharmacyDispenseRationaleProcess/story_html5.html

³ Prescribers must enter a Treatment Rationale if they wish to continue clozapine therapy when a patient's lab values indicate moderate or severe neutropenia. https://www.clozapinerems.com/CpmgClozapineUI/rems/videos/howToEnterATreatmentRationale/story_html5.html

⁴ <https://www.fda.gov/media/136317/download>